

Claims:

1. Method of treatment or prevention of menopausal complaints including osteoporosis, comprising administering to a patient in need thereof an effective amount of a pharmaceutical formulation in the form of an immediate-release peroral dosage unit, comprising, as the active substance, tibolone, wherein the formulation has a bioavailability, *in vivo*, of Org A at a level above that provided by a solution of tibolone as defined in the specification.
2. A solid pharmaceutical formulation comprising, as the active substance, tibolone and pharmaceutically acceptable excipients, characterized in that the tibolone has a mean particle size as defined in the specification of below 22.8  $\mu\text{m}$ .
3. A solid pharmaceutical formulation according to claim 2, characterized in that the mean particle size is below 20  $\mu\text{m}$ .
4. An immediate-release peroral solid dosage unit comprising, as the active substance, tibolone and pharmaceutically acceptable excipients, characterized in that the rate of dissolution of tibolone from dosage unit is such that when the dosage unit is subjected to a dissolution-test as described in the specification, the  $t_{50}$  value is below 23.1 minutes.
5. A dosage unit according to claim 4, characterized in that the  $t_{50}$  value is below 17 minutes.
6. A method of determining by means of an *in vivo* bioequivalence study whether a drug product comprising solid tibolone is bio-equivalent with another drug product comprising tibolone which is used as a standard tibolone product, the method comprising the steps of administering to a suitable test panel in a comparative trial the tibolone product of which the bioequivalence is to be determined and the standard tibolone product conducting an *in vivo* bioequivalence study, and measuring plasma levels of a measurable active substance, characterized in that the active substance is Org A.
7. A method according to claim 6, characterized in that the standard tibolone product is selected from the group consisting of 1.25 mg tibolone peroral immediate-release dosage unit Livial™ and 2.5 mg tibolone peroral immediate-release dosage unit Livial™.

8. A method according to claim 6, characterized in that the standard tibolone product is selected from the group consisting of 0.625 mg tibolone peroral immediate-release dosage unit Xyvion™ and 1.25 tibolone peroral immediate-release dosage unit Xyvion™.